

§ 886.4440

probes intended to locate metallic foreign bodies in the eye or eye socket.

(b) *Classification*. Class II.

§ 886.4440 AC-powered magnet.

(a) *Identification*. An AC-powered magnet is an AC-powered device that generates a magnetic field intended to find and remove metallic foreign bodies from eye tissue.

(b) *Classification*. Class II.

§ 886.4445 Permanent magnet.

(a) *Identification*. A permanent magnet is a nonelectric device that generates a magnetic field intended to find and remove metallic foreign bodies from eye tissue.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[52 FR 33355, Sept. 2, 1987, as amended at 53 FR 35606, Sept. 14, 1988; 66 FR 38813, July 25, 2001]

§ 886.4570 Ophthalmic surgical marker.

(a) *Identification*. An ophthalmic surgical marker is a device intended to mark by use of ink, dye, or indentation the location of ocular or scleral surgical manipulation.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

[52 FR 33355, Sept. 2, 1987, as amended at 53 FR 35606, Sept. 14, 1988; 59 FR 63013, Dec. 7, 1994; 66 FR 38813, July 25, 2001]

§ 886.4610 Ocular pressure applicator.

(a) *Identification*. An ocular pressure applicator is a manual device that consists of a sphygmomanometer-type squeeze bulb, a dial indicator, a band, and bellows, intended to apply pressure

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on the eye in preparation for ophthalmic surgery.

(b) *Classification*. Class II.

§ 886.4670 Phacofragmentation system.

(a) *Identification*. A phacofragmentation system is an AC-powered device with a fragmenting needle intended for use in cataract surgery to disrupt a cataract with ultrasound and extract the cataract.

(b) *Classification*. Class II.

§ 886.4690 Ophthalmic photocoagulator.

(a) *Identification*. An ophthalmic photocoagulator is an AC-powered device intended to use the energy from an extended noncoherent light source to occlude blood vessels of the retina, choroid, or iris.

(b) *Classification*. Class II.

§ 886.4750 Ophthalmic eye shield.

(a) *Identification*. An ophthalmic eye shield is a device that consists of a plastic or aluminum eye covering intended to protect the eye or retain dressing materials in place.

(b) *Classification*. Class I (general controls). When made only of plastic or aluminum, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 886.9. When made only of plastic or aluminum, the devices are exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180 of this chapter, with respect to general requirements concerning records, and § 820.198 of this chapter, with respect to complaint files.

[52 FR 33355, Sept. 2, 1987, as amended at 59 FR 63014, Dec. 7, 1994; 65 FR 2321, Jan. 14, 2000]

§ 886.4770 Ophthalmic operating spectacles (loupes).

(a) *Identification*. Ophthalmic operating spectacles (loupes) are devices that consist of convex lenses or lens systems intended to be worn by a surgeon to magnify the surgical site during ophthalmic surgery.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in